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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,028	03/22/2004	Robert Karlsson	B 521	1001

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EXAMINER	
GRUN, JAMES LESLIE	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,028	KARLSSON ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7,8,13,17-22,24-31 and 33-37* is/are pending in the application.

4a) Of the above claim(s) *30,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7,8,13,17-22,24-29,31 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 25 August 2008 is acknowledged and has been entered. Claims 2-4, 6, 9-12, 14-16, 23, 32, and 38-44 have been cancelled. Claims 1, 5, 7, 8, 13, 17-22, 24-31, and 33-37 remain in the case. Claims 30, 36, and 37 have been withdrawn from further consideration as being drawn to a non-elected species or invention. Claims 1, 5, 7, 8, 13, 17-22, 24-29, 31, and 33-35 are under examination.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 22, 24, 31, and 33-35 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth, in the absence of further written description and guidance from applicant, one would not be assured of the ability to practice the invention as instantly claimed because applicant merely assumes a critical micellar concentration (CMC) for the detergent, not the mixture, in the examples and

provides no evidence that a vesicular structure was formed at all concentrations of detergent and oligonucleotides mixtures used in the conditions of the experiment, particularly since the CMC for the detergent alone or, as known to the art, in the presence of DNA is higher than many, or at least several, of the concentrations used by applicant and asserted as containing micelles. Moreover, Chatterjee et al. (Biophys. Chem. 98: 313, 2002) also teach that high concentrations of cetyltrimethylammonium bromide (CTAB) relative to DNA, as used in the instant exemplifications, results in precipitation of DNA (see e.g. page 325). Thus, it is further unknown and unpredictable that the invention functions in the manner as claimed because an oligonucleotide target molecule complexed to a vesicular structure is unpredictable and not in evidence. Moreover, with regard to claim 22, applicant teaches a concentration ratio of oligonucleotide to CTAB of 1:61 (see e.g. pages 19-20), not about 61:1 as is now claimed.

Applicant's arguments filed 25 August 2008 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1, 5, 7, 8, 13, 17-21, 25-29, 31, and 33-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Cooper et al. (Anal. Biochem. 277: 196, 2000), Niemeyer et al. (Anal. Biochem. 268: 54, 1999), and Nikiforov et al. (US 5,610,287).

Cooper et al. teach sensor chips having 4 flow cells and having modified carboxymethyl dextran hydrogels, to which streptavidin was covalently bound (see e.g. page 203; SA sensor chips), deposited on a gold film for surface plasmon resonance determinations of molecule binding interactions. Biotinylated oligonucleotides in a high salt (1 M NaCl) buffer were bound to the immobilized streptavidin, washed, and used for binding to complementary nucleotides (see e.g. page 198). The reference also teaches layering of biotin and streptavidin for an oligonucleotide immobilization method involving negatively charged vesicles. In contrast to the invention as instantly claimed the reference does not teach cationic detergent solutions for immobilization of biotinylated oligonucleotides.

Niemeyer et al. also teach immobilization of biotinylated oligonucleotides to SA sensor chips or to streptavidin-coated microplate wells for immobilization of other components having complementary nucleotide portions. An immobilization buffer comprising salt was used (see e.g. page 56). In contrast to the invention as instantly claimed the reference does not teach cationic detergent containing compositions for immobilization of biotinylated oligonucleotides.

Nikiforov et al. teach compositions and methods for immobilization of oligonucleotides using the alternatives of cationic detergents or salts. The reference contacted mixtures of

cationic detergents, including cetyltrimethylammonium bromide (CTAB) (see e.g. col. 5) or1-ethyl-3-(3'-dimethylaminopropyl)-1,3-carbodiimide hydrochloride (EDC) (see cols. 7-8), with oligonucleotides for immobilization onto negatively-charged solid surfaces by either covalent or non-covalent binding (see e.g. cols. 14-16, Table 3). Different areas of the same solid support (wells in a microtitier plate) were treated similarly or differently. After immobilization, the detergent was washed away, leaving the immobilized oligonucleotides on the surface of the solid phase. However, the presence of vesicular structures in the mixture of EDC (see cols. 7-8) with oligonucleotides used in the immobilization of the oligonucleotides onto negatively-charged solid surfaces cannot be determined by the examiner.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have substituted compositions comprising cationic detergents for the salt containing solutions used in Cooper et al. or Niemeyer et al. for biotinylated oligonucleotide immobilization to immobilized streptavidin because Nikiforov et al. teach cationic detergent compositions as an alternative to salt containing compositions for oligonucleotide immobilization. One would have had an extremely reasonable expectation of success in using the cationic detergent reagents of Nikiforov et al. in the immobilization methods of Cooper et al. or Niemeyer et al. because Nikiforov et al. had already shown such reagents to be effective for oligonucleotide immobilization and one would have been motivated to have selected from known alternatives to perform the immobilization. Nothing unobvious is seen in the substitution of one known reagent for another to obtain the expected predictable result.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments filed 25 August 2008 have been fully considered but they are not deemed to be persuasive. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chatterjee et al. (Biophys. Chem. 98: 313, 2002) teach micelles of cetyltrimethylammonium bromide (CTAB) and deoxyribonucleic acid.

Reddy et al. (US 5,648,213) teach conventional alternatives for binding oligonucleotides to solid supports (see e.g. col. 10).

Karlsson et al. (Anal. Biochem. 300: 132, 2002) contacted a sensor surface, having a carboxymethyl-modified dextran hydrogel thereon, with mixed micelles comprising octylglucoside and lipids, considered herein a low molecular weight organic molecule. The mixed micelles of the method of the reference delivered the lipids to the surface of the sensor and immobilized the lipids thereto, as well as to the immobilized rhodopsin protein, when the octylglucoside was washed from the micelles. Thus the micelles complexed with an immobilized protein and contacted the sensor surface. After use, the surface was washed, leaving the immobilized protein disassociated from the components of the mixed micelles for re-use. Proteins such as the exemplified rhodopsin carry many charges, both positive and negative.

Czerkinsky et al. (J. Immunol. Meth. 65: 109, 1983) teach the enzyme-linked immunospot assay for the determination of antibody-secreting cells. Cells, considered herein as vesicular structures, suspected of containing antibodies are applied to a solid phase having bound thereon a member of a specific binding pair, antigen, to bind target molecule, antibody, released from the cells. Different antigens are bound to different surfaces. Different antibodies are produced by different cells. The antibodies are bound to antigen on the solid phase surface, the cells are removed, and the bound antibodies are detected at discrete locations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
December 25, 2008

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641